AUG 17 2007

SECTION IV

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

**BIORAPTOR PK Suture Anchor**

Date Prepared: 06 AUG 2007

**A. Submitter's Name:**

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover, MA 01810

**B. Company Contact**

Julie Acker, RAC

Regulatory Affairs Specialist

Phone: (508) 261-3618

FAX: (508) 261-3620

**C. Device Name**

| | |
|---|---|
| Trade Name: | BIORAPTOR 2.3 PK Suture Anchor |
| Common Name: | Fastener, fixation, non-degradable, soft tissue |
| Classification Name: | Smooth or threaded metallic bone fixation fastener |
| Product Code: | MBI |
| Regulation Number: | 21 CFR §888.3040 |

**D. Predicate Devices**

The Smith & Nephew BIORAPTOR 2.3 PK Suture Anchor is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution: BIORAPTOR 2.3 OC Suture Anchor (K063726) and KINSA Suture Anchor (K061154).

**E. Description of Device**

Non-bioabsorbable 2.3 mm suture anchor manufactured from PEEK Optima® polymer with attached non-bioabsorbable ultra high molecular weight braided polyethylene #2 suture preassembled to a stainless steel inserter.

## F. Intended Use

These suture anchors are intended for the fixation of soft tissue to bone in the Hip, Shoulder, Foot, Ankle, Elbow, Wrist, Hand and Knee as follows:

**Hip**
Hip capsule repair
- Acetabular labrum reattachment

**Shoulder**
Capsular stabilization
- Bankart repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions
Acromioclavicular separation repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

**Foot and Ankle**
Hallux valgus repairs
Medial or lateral instability repairs/reconstructions
Achilles tendon repairs/reconstructions
Midfoot reconstructions
Metatarsal ligament/tendon repairs/reconstructions
Bunionectomy

**Elbow, Wrist, and Hand**
Biceps tendon reattachment
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair

**Knee**
Extra-capsular repairs:
– Medial collateral ligament
– Lateral collateral ligament
– Posterior oblique ligament
Patellar realignment and tendon repairs
– Vastus medialis obliquous advancement
Iliotibial band tenodesis

## G. Comparison of Technological Characteristics

The Smith & Nephew BIORAPTOR PK Suture Anchor is substantially equivalent to the Smith & Nephew BIORAPTOR OC Suture Anchor (K063726). The BIORAPTOR PK anchor design is identical to that of the predicate anchor (K063726). The only difference is the anchor material which is a non-biodegradable polymer. This material is identical to that used in the Smith & Nephew KINSA Suture Anchor (K061154).

## H. Summary Performance Data

The performance testing conducted demonstrates that the insertion and fixation properties of the BIORAPTOR PK anchor are substantially equivalent to the Smith & Nephew BIORAPTOR OC and the Smith & Nephew KINSA anchors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Ms. Julie Acker, RAC
150 Minuteman Rd.
Andover, MA 01810

AUG 17 2007

Re: K071586
Trade/Device Name: BIORAPTOR 2.3 PK Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: August 6, 2007
Received: August 7, 2007

Dear Ms. Acker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K071586

Device Name: BIORAPTOR 2.3 PK Suture Anchor

The Smith & Nephew BIORAPTOR Suture Anchor is intended for the reattachment of soft tissue to bone for the following indications:

**Hip**
Hip capsule repair
- Acetabular labrum reattachment

**Shoulder**
Capsular stabilization
- Bankart repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions
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**Elbow, Wrist, and Hand**
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**Knee**
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– Medial collateral ligament
– Lateral collateral ligament
– Posterior oblique ligament
Patellar realignment and tendon repairs
– Vastus medialis obliquous advancement
Iliotibial band tenodesis

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruehlow

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K071586